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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,831	04/04/2002	Nathan W Levin	BET-105	5604

23520 7590 03/22/2005

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/089,831	Applicant(s) LEVIN ET AL. <span style="float: right;">ED</span>	
	Examiner Michael J. Hayes	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11 and 21-36 is/are allowed.
- 6) ☒ Claim(s) 12, 14-20 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/05/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 14-20, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over PEABODY (US Patent No. 5,643,201) in view of HAGEN (US Patent No. 4,059,169).

Peabody discloses a method for computer-controlled continuous peritoneal dialysis including controlling flow rates, fluid composition, and fluid conductivity. Peabody discloses monitoring the fluid flow to fill the patient's cavity with a prescribed volume of fluid. *See col. 3, line 50 - col. 4, line 52; 5:6-20, 34-37; 8:6-11, 49-67, 10:8-24.* Peabody discloses using ultrasonic sensing or resistive sensing devices to determine fluid volume in the peritoneal cavity for controlling the dialysis procedure. *See 4:46-52, 8:6-16.* Peabody does not state using bioimpedance measurement for determining fluid volume. Hagen teaches the use of bioimpedance measurements to determine body fluids (*See 2:10-16*). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Hagen in the method of Peabody in order to achieve an accurate measurement of body fluid. Additionally, Hagen shows what was of common knowledge in the field of body fluid measurements.

With respect to claims 17-20 where the procedure is performed for three or six hours and measurements are taken continuously, it would have been obvious to one of ordinary skill in the

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art to select different times to achieve the desired treatment. The step of taking measurements continuously or at some frequency would be an obvious design choice within the knowledge of one of ordinary skill in the art. Applicant has not established any criticality nor any unexpected results associated with these times or frequency.

With respect to claims 37-39 Applicant merely recites a computer for performing a step described as a mathematical equation. The examiner interprets these claims to read on a computer that is capable of performing such equations because the specific step equations are not explicitly recited in the claims. Since all computers have the capability to have these equations programmed in, the claims read on any computer.

### ***Response to Arguments***

Applicant recognizes that Peabody describes a “continuous” process, though Applicant feels that Peabody does not describe a true “continuous” process. Applicant has not explicitly defined “continuous” in his specification, so the term is given its broadest reasonable interpretation. Peabody has a portion of the process where fluid flows continuously through a subject’s cavity. Claim 12 is given its broadest reasonable interpretation that at some point in the process fluid continuously flows through a patient. Applicant has not sufficiently distinguished his method of claim 12 from the prior art. Applicant should more clearly recite what he means by “continuously flowing” in the claim.

Applicant’s arguments that one particular reference experienced trouble with whole-body bioimpedance measurements is not persuasive to withdraw the rejection of claim 12 with the teaching of Hagen to use bioimpedance measurements. Applicant’s statement that bioimpedance

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measurements had been rejected by workers in the art may only apply to some workers and only to certain methods of bioimpedance measurements. Additionally, Applicant does not argue that the bioimpedance method can't work, only that this whole-body bioimpedance measurement method is troublesome. Hagen teaches the use of bioimpedance measurement to readily indicate fluid changes of biologic volumes.

### *Allowable Subject Matter*

Claims 1-11, 21-36 are allowed.

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 34-36 are allowable because they recite a computer code means for performing specifically described steps embodied on a computer useable medium. It is clear from Applicant's specification and remarks (received 1/06/05) that the computer useable medium is a tangible medium, such as magnetic or optical discs (see specification, pg. 13, lines 22-25).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PACELA (US Patent No. 3,871,359) discloses the use of bioimpedance measurements for fluid changes within a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be

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reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
19 March 2005

  
MICHAEL J. HAYES  
PRIMARY EXAMINER